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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,934	11/15/2001	Zoltan Nagy	GPCG-P01-003	8886

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EXAMINER

CANELLA, KAREN A

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/001,934	<b>Applicant(s)</b> NAGY ET AL.	
	<b>Examiner</b> Karen A. Canella	<b>Art Unit</b> 1643	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on May 16, 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 24-29, 82-87, 117, 118, 124 and 125 is/are allowed.
- 6) ☐ Claim(s) 7-23, 33-37, 43, 55, 56, 59-63, 67, 71-79, 81, 92-95, 120-123 and 126-129 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims pending in the application are 7-29,33-37,43,55,56,59-63,67,71-79,81-87,92-95,117,118 and 120-129.

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### **DETAILED ACTION**

Claims 14-18, 20, 22-24, 26, 28, 71, 73-78, 81, 82, 84, 86, 92, 120, 121, 123 and 126 have been amended. Claims 7-29, 33-37, 43, 55, 56, 59-63, 67, 71-79, 81-87, 92-95, 117, 118, 120-129 are pending and under consideration.

The finality of the Office action of February 14, 2005 is withdrawn in light of the rejections below.

Text of Title 35, U.S. code not found in this action can be found in a prior action.

The specification is objected to for lack of compliance to the Sequence Rules and the incorporation of new matter. The disclosure as filed provides support for the VH domain of GPC-1, which is QYGHRGGFDH (residues 100-109 of SEQ ID NO: 37, Sequence Listing filed July 18, 2002); GPC-6 which is GYGRYSPDL (residues 99-107 of SEQ ID NO:39, Sequence Listing filed July 18, 2002); GPC-10, which is QLHYRGGFDL (residues 100-109 of SEQ ID NO:43, Sequence Listing filed July 18, 2002), and GPC-8-6-45, GPC-8-6-13, GPC-8-6-47, GPC-8-10-57, GPC-8-27-7, GPC-9-27-41, GPC-8, GPC-8-1, GPC-8-6, GPC-8-9, GPC-8-10, GPC-8-17, GPC-8-18, GPC-8-27, GPC-8-6-2, GPC-8-6-19, and GPC-8-6-27 all of which have a VH domain which is SPRYRGAFDY (residues 100-109 of SEQ ID NO:41, Sequence Listing filed July 18, 2002). The disclosure as filed provides support for the VL domain of GPC-1, QSYDFNES (residues 90-97 of SEQ ID NO:38, Sequence Listing filed July 18, 2002); GPC-6 which is QQYSNLPF(residues 90-97 of SEQ ID NO:40, Sequence Listing filed July 18, 2002); QPC-10, which is QSYDLTMG (residues 90-97 of SEQ ID NO:44, Sequence Listing filed July 18, 2002); GPC-8-6-45, QSYDYDHY (residues 90-97 of SEQ ID NO:51, Sequence Listing filed July 18, 2002); GPC-8-6-13, QSYDYDHY (residues 90-97 of SEQ ID NO:54, Sequence Listing filed July 18, 2002); GPC-8-6-47, QSYDYDHY (residues 90-97 of SEQ ID NO:53, Sequence Listing filed July 18, 2002); GPC-8-10-57, QSYDLIRH (residues 90-97 of SEQ ID NO: 56, Sequence Listing filed July 18, 2002); GPC-8-27-7, QSYDMNVH (residues 90-97 of SEQ ID NO:55, Sequence Listing filed July 18, 2002); GPC-9-27-41, QSYDMNVH (residues 90-97 of SEQ ID NO:58, Sequence Listing filed July 18, 2002); GPC-8, which is QSYDMPQA (residues

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90-97 of SEQ ID NO:42, Sequence Listing filed July 18, 2002); GPC-8-1, which is QSYDFSHY, wherein the QSYDFSH is residues 90-96 of SEQ ID NO:48, however the residue which follows the "H" in SEQ ID NO:48 is "V", not "H" as indicated; GPC-8-6, which is QSYDYDHY (residues 90-97 of SEQ ID NO:46, Sequence Listing filed July 18, 2002); GPC-8-9, which is QSYDIQLH (this sequence is not in SEQ ID NO:31, Sequence Listing filed July 18, 2002); GPC-8-10, which is QSYDLIRH (residues 90-97 of SEQ ID NO:48, Sequence Listing filed July 18, 2002); GPC-8-17, which is QSYDFSVY (residues 90-97 of SEQ ID NO:50, Sequence Listing filed July 18, 2002); GPC-8-18, which is QSYDFSIY (this sequence is not in SEQ ID NO:31); GPC-8-27, which is QSYDMNVH (residues 90-97 of SEQ ID NO:52, Sequence Listing filed July 18, 2002); GPC-8-6-2, which is QSYDYDHY (residues 90-97 of SEQ ID NO:45, Sequence Listing filed July 18, 2002); GPC-8-6-19, which is QSYDYDHY (residues 90-97 of SEQ ID NO:47, Sequence Listing filed July 18, 2002); and GPC-8-6-27, which is QSYDYDHY (residues 90-97 of SEQ ID NO:47, Sequence Listing filed July 18, 2002).

(A) The specification fails to comply with the sequence rules because QSYDFSHY in GPC-8-1, QSYDIQLH in GPC-8-9 and QSYDFSIY in GPC-8-18 do not have the correct Sequence Identifiers.

(B) The Specification is objected to for the incorporation of new matter because the disclosure of the CDR regions of the isolated clones on Table 1, does not provide adequate support for the entire sequence comprising the clone. The sequence of a single CDR region is a fraction of the total sequence of the clone comprising said CDR. The art teaches no nexus between the CDR sequence and the remainder of the framework region within said clone, therefore one of skill in the art would not been able to envisage the entirety of the cloned sequences beyond that of the disclosed CDR regions. One of skill in the art would reasonable conclude that applicant was not in possession of the entirety of the full length SEQ ID NO at the time the application was filed.

(C) Further, the Sequence Listing filed August 1, 2003 enters new matter into the disclosure because said sequences differ substantially from those in the Sequence Listing filed July 18, 2002. For instance in the 7/18/02 listing, SEQ ID NO:37 is 120 amino acids in length; in the 8/1/03 listing SEQ ID NO:37 is 13 amino acids in length. Further, Table 1 has been amended on November 15, 2004 to recite SEQ ID NO for the CDR sequences within the clones on which the instant method claims depend. It is noted that claim 22 requires that the VH and VL domains of

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the GPC-1 clone be SEQ ID NO:37 and 38. Table 1 indicates that the GPC-1 clone has a VH CDR sequence of SEQ ID NO:19 and a VL CDR sequence of SEQ ID NO:59, however, neither CDR sequence can be found within the VH and VL sequence of SEQ ID NO:37 and 38 according to the Sequence Listing filed August 1, 2003.

Claims 7-23, 33-37, 43, 55, 56, 59-63, 67, 71-79, 81, 92-95, 120-123, 126-129 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 7-23, 33-37, 43, 55, 56, 59-63, 67, 71-79, 81, 92-95, 120-123, 126-129 are drawn to compositions comprising full length sequences of the variable chains of SEQ ID NO:37 and SEQ ID NO:38; SEQ ID NO:39 and SEQ ID NO:40; SEQ ID NO:43 and SEQ ID NO:44; SEQ ID NO:41 and SEQ ID NO:42, 28, 46, 31, 48, 50, 31, 52, 45, 47, 49, 51, 54, 53, 56, 55, 57, or 58. Said sequences were introduced in the Sequence Listing filed July 18, 2002. The specification provides adequate support for a multivalent polypeptide having two or more antigen binding domains which include a combination of CDR residues as part of a VH and VL domain selected from residues 100-109 of SEQ ID NO:37 and residues 90-97 of SEQ ID NO:38, residues 99-107 of SEQ ID NO:39 and residues 90-97 of SEQ ID NO:40, residues 100-109 of SEQ ID NO:43 and residues 90-97 of SEQ ID NO:44; and residues 90-97 of SEQ ID NO:42 in combination with any of QSYDFSHY, residues 90-97 of SEQ ID NO:46, QSYDIQLH, residues 90-97 of SEQ ID NO:48, residues 90-97 of SEQ ID NO:50, QSYDFSIIY, residues 90-97 of SEQ ID NO: 52, residues 90-97 of SEQ ID NO:45, residues 90-97 of SEQ ID NO:47, residues 90-97 of SEQ ID NO:49, residues 90-97 of SEQ ID NO:51, residues 90-97 of SEQ ID NO:54, residues 90-97 of SEQ ID NO:53, residues 90-97 of SEQ ID NO:53, residues 90-97 of SEQ ID NO:56, residues 90-97 of SEQ ID NO:56, residues 90-97 of SEQ ID NO:55 or residues 90-97 of SEQ ID NO:58 in the VH and VL CDR sequence disclosed in Table 2. However, the specification and claims as filed fail to provide support for a multivalent polypeptide comprising the entirety of SEQ ID NO:37 and SEQ ID NO:38; SEQ ID NO:39 and SEQ ID NO:40; SEQ ID NO:43 and SEQ ID NO:44; or SEQ ID NO:41 and SEQ ID NO:42, 28, 46, 31, 48, 50, 31, 52, 45, 47, 49, 51, 54, 53,



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56, 55, 57, or 58. For the reasons stated in the objection to the specification above, disclosure of a CDR sequence in the originally filed specification does not adequately describe an antibody based variable chain sequence, because said variable chain comprises framework region sequences which are extraneous to the CDR sequence and which have no direct nexus to the sequence of the CDR regions. One of skill in the art would reasonably conclude that applicant was not in possession of the entirety of the claimed variable chain sequences at the time the application was filed.

Claims 24-29, 82-87, 117, 118, 124 and 125 are allowed.

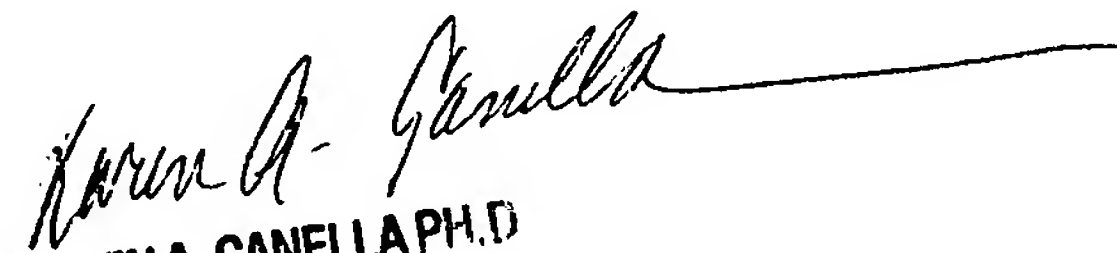
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 11 am to 10 pm, except Wed, Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Karen A. Canella, Ph.D.

1/5/2006

  
KARENA. CANELLA PH.D.  
PRIMARY EXAMINER